

52. In a method for treating urological and gastric disorders comprising the step of injecting submucosally or peri-urethrally into tissue at at least one injection site a composition comprising an effective amount of micro particles dispersed in a compatible physiological vehicle, the improvement comprising the steps of:

selecting relatively malleable biologically compatible micro particles consisting essentially of a polysiloxane material, the micro particles having an average undimensional particle size above 60 microns and a highly irregular particle surface configuration including indentations, cavities and pores which cooperate in an autogenous manner to essentially prevent loss of the micro particles from an injection site;

selecting a compatible physiological vehicle that will promote injection of the micro particles but once injected need not be particle relative.

REMARKS

In accordance with the above amendments, existing Claims 1-30 have been cancelled, without prejudice, and replaced by new Claims 31-52. The new claims are believed to more clearly define applicants' invention and clarify language and distinctions with respect to the art.

Applicants believe that the present amendment should be entered inasmuch as it is believed to put the claims in condition for allowance or, if such becomes necessary, put the claims in a

better condition for pursuing an appeal. The number of claims has been reduced from 30 to 22, thereby simplifying the issues on appeal.

It is noted that all but three of the previously submitted claims stand rejected under 35 U.S.C. §103 as being unpatentable over several Politano and Politano et al publications in view of Ersek, et al. all previously cited in this application, Ersek et al. having not been previously applied. It is the Examiner's position that process for treating urinary or gastric disorders is generally disclosed by Politano and that Ersek et al. recognize the problems with migration of injected material and studied the effects of texturized particles for augmenting soft tissue in which tissue growth about the particles increased particle retention in the area of augmentation. Therefore, it follows that it would have been obvious to use texturized particles in the treatment of urinary incontinence.

Applicants do not believe that this is the case. Applicants were careful to point out in their previous response (paper no. 7) that the success obtained by the injection of polytetrafluoroethylene (PTFE) micro particulate matter with respect to long term alleviation of urinary incontinence, and other chronic disorders, has been far from uniform. Much subsequent documented experience indicates the existence of serious drawbacks with respect to particulate migrations and subsequent granulomatous reactions as reported by Malizia, Jr. et al cited in applicants'

previous amendment. It is believed that there is a high degree of unpredictability with regard to any such micro particulate injection treatments.

While the Ersek et al reference reports successful augmentation of soft tissue of the face and extremities using an injection injectable composition including textured micro implants, it clearly does not deal with the long-term augmentations of tissues related to correcting urological and gastric disorders such as incontinence or reflux. Applicants submit that in view of the limited success of Politano with respect to the injection of particulate matter at all the recognition by Ersek et al. that textured micro implants may be used to augment a certain class of soft tissues, in a manner which precludes migration of the particles, does not make it obvious that the textured micro implants would be successful in the treatment of the aforementioned urological and gastric disorders.

Applicants believe that the obviousness suggested with respect to the present invention is a conclusion rather than a reason based on the teachings in the art. It is believed that only through hindsight and given the teachings of the present specification that the suggested combination would be rendered obvious.

With respect to the three claims directed toward the use of polyvinylpyrrolidone (PVP) as an injection vehicle, now Claims 37, 47 and 50, and it is believed that these claims are clearly patentable and not rendered obvious by the above combination or by

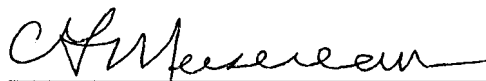
that combination further in view of the newly-applied Henderson et al reference in U.S. Patent 4,828,827. That reference discloses an acquious gel of cross-linked PVP used to augment soft tissue in mammals. It is clear that the PVP of the present invention is meant to be a vehicle only and not to participate in the long-term tissue augmentation. It is not known how the cross-linked PVP tissue augmentation material of Henderson et al. would, in that hydrogel state, function in replacing the glycerine and polysorbate found in the Politano et al. composition. In any event, there is clearly no reason to be derived from a careful reading of the Politano references which would lead one to replace the glycerine and polysorbate combination with PVP. This is true after studying all of the references including Henderson et al inasmuch as lubricity and biocompatibility are clearly not problems with respect to the glycerine and polysorbate materials of Politano. There is no reason one would be led to make the suggested combination or substitution based on the references, therefore, it is believed no prima facia case of obvious can be maintained.

Applicants believe that present amendments have clarified distinctions between their claimed invention and the prior art and that their particular process or method including the particular composition injected, represents a definitive step forward over prior methods of treating the chronic problems involved. The success of this approach is believed to be something that could not accurately be predicted based on the cited teachings and resents

significant steps forward. It is believed that the present amendment should be entered and the claims allowed.

Respectfully submitted,

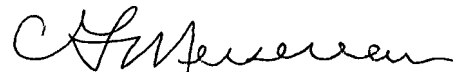
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CERTIFICATE OF MAILING

I hereby certify that the foregoing AMENDMENT UNDER 37 CFR 1.116 in response to the Official Communication of Paper No. 8, in application Serial No. 07/863,848, filed on April 6, 1992, of Robert A. Ersek et al entitled "TREATMENT OF UROLOGICAL AND GASTRIC FLUID REFLUX DISORDERS BY INJECTION OF MICRO PARTICLES" is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to Commissioner of Patents and Trademarks, Washington, D.C. 20231, postage prepaid, on April 1, 1993.



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Date of Signature: April 1, 1993